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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/672,519      | 09/27/2000  | Bruce W. Gibbs       | BC-0256-P02         | 2122             |

24994 7590 06/29/2005

GAMBRO, INC  
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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 06/29/2005

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/672,519  
Filing Date: September 27, 2000  
Appellant(s): GIBBS, BRUCE W.

**MAILED**

**JUN 29 2005**

**Group 3700**

\_\_\_\_\_  
Laura Butterfield

For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed December 20<sup>th</sup>, 2004.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

Appellant's brief includes a statement that claims 1-6 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

|              |                 |         |
|--------------|-----------------|---------|
| 6,200,287 B1 | Keller et al.   | 03-2001 |
| 5,009,654    | Minshall et al. | 04-1991 |

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

A). Claims 1 and 5-6 are rejected under 35 U.S.C. 102(e) based on Keller et al. (6,200,287). This rejection is set forth in a prior Office Action, mailed on 07/26/2004.

B). Claim 2 is rejected under 35 U.S.C. 103(a) based on Keller et al. (6,200,287). This rejection is set forth in a prior Office Action, mailed on 07/26/2004.

C). Claims 3 and 4 are rejected under 35 U.S.C. 103(a) based on Keller et al. (6,200,287) in view of Minshall (5,009,654). This rejection is set forth in a prior Office Action, mailed on 07/26/2004.

**(11) Response to Argument**

A). With respect to the rejection of claims 1, 5 and 6, Applicant argues that Keller does not disclose a disposable having a preconnected red blood cell filter (pg. 5, section

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VIII (A) of appeal brief). None of the claims recite a red blood cell filter; however, claim 1 does recites a leukoreduction filter as part of the disposable. Therefore, the arguments have been treated as being directed to a leukoreduction filter. Applicant further argues that the mere possibility that Keller's teaching that a leukoreduction filter "can be connected" to the disposable does not inherently imply that the filter is preconnected or integrated into the disposable as claimed.

With respect to the recitation that the filter is preconnected between the red blood cell (RBC) collection bag and the RBC storage bag, it is the position of the Examiner that Keller meets this limitation. Keller discloses an embodiment of using the disposable wherein it is desirable to filter out leukocytes from the collected RBC. Keller teaches that the RBC are collected into a collection bag or reservoir, the bag is connected to a commercially available filter to filter out the leukocytes, and the filtered RBC product is then transferred into a new storage bag (see col. 55, lines 20-39). In order to carry out the leukocyte filtration, one would have to connect the filter to the tubing and a storage bag resulting in a preconnected or interconnected leukoreduction filter. Regardless of when the connection of the filter is made, the filter is preconnected between the collection bag and the storage bag.

With respect to the argument that the teaching in Keller that a leukoreduction filter "can be connected" to the disposable does not inherently imply that the filter is preconnected or integrated into the disposable as claimed the Examiner respectfully disagrees. Keller discloses multiple embodiments of the disposable set. Keller states that if it is desired, RBC can be or may be passed through a filter before storage to

remove leukocytes. This is a teaching for connecting a leukocyte filter to the disposable. Again, in order to carry out the leukocyte filtration, one would have to connect the filter to the tubing and a storage bag resulting in a preconnected or interconnected leukoreduction filter. Regardless of when the connection of the filter is made, the filter is preconnected between the collection bag and the storage bag.

B). With respect to the rejection of claim 2, Applicant argues that Keller does teach of an air removal bag interconnected to the red blood cell storage bag and that the prior art does not provide motivation or reason for rearranging the parts of the invention as set forth in the rejection. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Keller teaches that instead of the vent bag assembly being connected to the reservoir of the assembly, other integral passageways, integrated chambers, and tubing loops could be used as part of the assembly to perform the same functions as the vent bag tubing assembly, that of receiving sterile air out of the assembly. Therefore, the motivation to rearrange the connection of an air removal bag to the RBC storage bag is provided.

C). With respect to the rejection of claims 3 and 4, Applicant argues that Minshall does not disclose the use of a frangible connector to enable red blood cells to pass through the tubing between a filter and a RBC collection bag (claim 3) nor does Minshall disclose frangible connectors for the connections between the RBC collection bag and a storage solution container (claim 4). Applicant further argues that the tubing of invention is a single distinct piece of tubing which contains the frangible connector.

Minshall discloses a disposable assembly for use in a medical fluid process, such as a closed apheresis circuit (see col. 4, lines 58-63). A processing apparatus has multiple tubing segments, each having end portions that are frangible closures to maintain a sealed, sterile tube (col. 6, lines 25-42). Keller teaches that the tubing of the system may be employed for sterile docking of tubing, that is the direct connection of two pieces of tubing (col. 20, lines 9-11). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to modify the tubing of Keller with frangible connectors as taught by Minshall is to provide a sterile connector for the tubing.

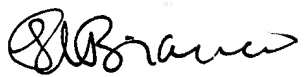
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In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tubing of invention is a single distinct piece of tubing which contains the frangible connector) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

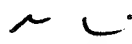
Patricia M Bianco  
Primary Examiner  
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June 20, 2005

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